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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,919	11/21/2001	Roberto Macina	DEX-0289	2841

7590 05/02/2003  
Licata & Tyrrell P.C.  
66 East Main Street  
Marlton, NJ 08053

EXAMINER
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MARTINELL, JAMES

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/989,919

**Applicant(s)**

MACINA ET AL.

**Examiner**

James Martinell

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 14/1, and 15/1 drawn to nucleic acids, nucleic acid molecular hybridization assays, vectors, host cells, kits, and methods for producing polypeptides, classified in class 536, subclass 23.5 and class 435, subclasses 252.3, 325, 320.1, and 69.1.
- II. Claims 10 and drawn to polypeptides, classified in class 530, subclass 350.
- III. Claims 12, 13, 14/6, and 15/6 drawn to antibodies, antibody assays, and kits, classified in class 530, subclass 387.1 and class 435, subclass 7.1.
- IV. Claim 16 drawn to methods of treatment using antibodies, classified in class 514, subclass 2.
- V. Claim 17 drawn to polypeptide vaccines, classified in class 514, subclass 12.
- VI. Claim 17 drawn to polynucleotide vaccines, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons. The nucleic acids, vectors, host cells, and kits of Group I are materially different from, and are therefore independent and distinct from, the polypeptides of Group II, the antibodies of Group III, and the polypeptide vaccines of Group V. The methods of Group I may be practiced independently of the methods of Groups III and IV. The methods of Group I are not needed to produce the polypeptides of Group II, which polypeptides may be isolated from naturally occurring sources or may be chemically synthesized. Similarly, the methods of Group I are not needed to make the polypeptide vaccines of Group V. The methods of Group I are not needed to make the antibodies of Group III. The products in Group I are not needed to practice the methods of either one of Groups III or IV. The nucleic acids, vectors, host cells, and kits of Group I have uses other than to make the polynucleotide vaccines of Group VI. For example, the nucleic acids, vectors, host cells, and kits of Group I may be used in affinity chromatography. The polypeptides of Group II are materially different from, and are therefore independent and distinct from, the antibodies of Group III and the polynucleotide vaccines of Group VI. The polypeptides of Group II are not needed to practice the methods of Groups III or IV. The polypeptides of Group II have uses

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other than to produce the polypeptide vaccines of Group V. For example, the polypeptides of Group II may be used in affinity chromatography. The antibodies of Group III are materially different from, and are therefore independent and distinct from, the polypeptide vaccines of Group V and the polynucleotide vaccines of Group VI. The methods of Group III may be practiced independently of the methods of Group IV. The antibodies of Group III have uses other than in the methods of Group IV. For example, the antibodies of Group III may be used in affinity chromatography. The methods of Group IV do not require the polypeptides of Group V or the polynucleotides of Group VI. The polypeptide vaccines of Group V are materially different from the polynucleotide vaccines of Group VI. Thus, Groups V and VI are independent and distinct even though they are recited within the same claim.

Claims 1-9, 14/1, 15/1, and 17 are drawn to nucleotides, nucleotide constructs, and/or methods requiring the use of nucleotides or nucleotide constructs that contain more than one individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121 as outlined in 1192 O.G. 68 (November 19, 1996). This notice permits the examination of from one to ten independent and distinct nucleotide sequences in a single application based upon USPTO resources.

Applicant is required to select no more than ONE of the individual sequences for examination. The search of the no more than ONE selected sequence may include the complement of the selected sequence and, where appropriate, may include subsequences within the selected sequence (*e.g.*, oligomeric probes and/or primers).

Claims 10-13, 14/6, 15/6, 16, and 17 are drawn to more than one unrelated, independent, and distinct polypeptide or methods requiring the use of more than one unrelated, independent, and distinct polypeptide. Should applicants elect any one of Groups III-V for examination, applicants are further required to select one polypeptide or a set of methods that requires the use of only one polypeptide for examination on the merits.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

To search any two groups as outlined above would create an undue burden for the U.S. PTO because the searches of the non-patent literature are not only non-overlapping to any appreciable extent, but are also divergent in nature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

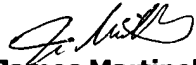
Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1633 at (703) 308-4242. The faxing of such papers must conform to the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to [james.martinell@uspto.gov](mailto:james.martinell@uspto.gov). Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



**James Martinell, Ph.D.**  
**Primary Examiner**  
**Art Unit 1631**